510(k) Summary

DEC 7 2012

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. Name and Address of Applicant

Avinger, Inc.
400 Chesapeake Drive
Redwood City, CA 94063

B. Contact Person

Albert Boniske
Sr. Manager, Regulatory and Quality Affairs
(650) 241-7004

C. Date Prepared

November 8, 2012

D. Device Name

Trade Name:	Ocelot Catheter
Common Name:	Percutaneous Catheter
Classification Name:	Percutaneous Catheter

E. Device Classification

Classification:	21 CFR §870.1250
Product Code:	DQY
Device Class:	Class II

F. Predicate Device

The Ocelot Catheter is substantially equivalent to the original Ocelot Catheter (K122380).

G. Device Description

The Ocelot System consists of the Ocelot Catheter, the Lightbox Console and the Umbilical. The Ocelot Catheter is an over-the-wire device that is compatible with a 6F sheath and 0.014" guidewire. The Ocelot Catheter has a working length of 110cm and incorporates an optical fiber used to facilitate Optical Coherence Tomography (OCT)-assisted orientation as an adjunct to fluoroscopy.

H. Intended Use

The Ocelot System is intended to facilitate the intraluminal placement of conventional guidewires beyond stenotic lesions (including sub and chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention using OCT-assisted orientation as an adjunct to fluoroscopy. The Ocelot System is contraindicated for use in the iliac, coronary, cerebral, renal or carotid vasculature.

I. Substantial Equivalence

The Ocelot Catheter is substantially equivalent to the originally cleared Ocelot Catheter (K122380). The subject and predicate devices have the same mechanism of action (manual advancement) and perform the same function (placement of guidewires beyond stenotic lesions in the peripheral vasculature). The design changes implemented to create Ocelot NEXT include a slightly larger torque coil and modified torque shaft, a longer hypotube in the handle assembly, a strain relief just distal to the rotator knob, the addition of a coil around the shaped distal segment and a modified spiral flute design in the distal tip. The modified distal tip represents a hybrid between the original Ocelot Catheter spiral flute configuration and the Wildcat Catheter's bilateral wedges (K111338). The changes to the Ocelot Catheter cleared under K122338 results in no significant changes to technological characteristics and do not raise any new issues of safety or effectiveness.

J. Non-Clinical Performance Data

The following non-clinical testing was previously conducted with the Ocelot Catheter to support a determination of substantial equivalence to the predicate device. Tip penetration testing was performed to ensure the catheter did not advance when the tip is engaged in tissue.

• Visual and Dimensional Verification	• Spiral Blade Functional Testing
• Tensile Testing	• Coating Friction Testing
• Torque Testing	• Tip Penetration Testing
• Guidewire advancement	• In Vitro Simulated Use Testing
• Device Advancement	• Shelf Life Testing
• Tip Deflection Testing	• Tip-Stall Testing
• Device leak testing	• Tip Penetration Testing
• Luer Leak Testing	• Flexibility/Trackability

The above testing confirmed that the Ocelot Catheter performs according to the stated intended use. All data fell well within pre-determined product specifications

and external standard requirements. Results of non-clinical testing demonstrated that the Ocelot Catheter is substantially equivalent to the predicate device for the stated intended use.

K. Conclusions

The Ocelot Catheter has been carefully compared to legally marketed devices with respect to intended use and technological characteristics. Non-clinical testing was conducted to validate the performance of the devices and ensure the Ocelot Catheter functions as intended and meet design specifications. The comparison and non-clinical results demonstrate that the devices are substantially equivalent to the predicate device for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Avinger, Inc.
Mr. Albert Boniske
Sr. Manager, Regulatory and Quality Affairs
400 Chesapeake Drive
Redwood City, CA 94063

SEP 18 2013

Re: K123462
Trade/Device Name: Ocelot Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: November 8, 2012
Received: November 9, 2012

Dear Mr. Boniske:

This letter corrects our substantially equivalent letter of December 7, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K 123462

Device Name: Ocelot Catheter

Indications for Use:

The Ocelot System is intended to facilitate the intraluminal placement of conventional guidewires beyond stenotic lesions (including sub and chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention using OCT-assisted orientation as an adjunct to fluoroscopy. The Ocelot System is contraindicated for use in the iliac, coronary, cerebral, renal or carotid vasculature.

Prescription Use X **Or** **Over-The-Counter Use** _____

(per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K123462